UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSES AND OBJECTIONS TO PLAINTIFFS'
FIRST AMENDED NOTICE OF 30(b)(6) DEPOSITION OF ETHICON, LLC

Defendant Ethicon, LLC hereby responds and objects to Plaintiffs' first amended notice to take the oral deposition of Defendant through designated witnesses pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure.

The notice at issue is attached as Exhibit "A." It purports to identify the areas in which Defendant's representatives will testify at deposition and relates to Ethicon, LLC's company structure and organization, manufacturing and distribution practices, outside contractors/ consultants, and regulatory communications. As an initial matter and as noted in its discovery responses, Ethicon, LLC is a manufacturing facility. It has entered into a Quality Agreement with Ethicon, Inc. and Medical Device and Diagnostics Global Services, LLC ("MD&D") whereby those entities with expertise in different areas provide certain services to Ethicon, LLC. Ethicon, LLC utilizes the services provided by MD&D for quality supervision and oversight of the manufacture of relevant products. Ethicon, LLC utilizes the services provided by Ethicon, Inc. for Research & Development, New Product Development, Design Control, Risk

Management, Regulatory Affairs, Complaint Management and Post Market Surveillance of relevant products. Defendant has provided Plaintiffs with a copy of the Quality Agreement.

Further, Ethicon, LLC is not involved in any manner with the manufacture of any of the TVT family of products or any pelvic mesh with an absorbable component such as Prolift +M; Ethicon, LLC's only relevant "finished" product is Gynemesh PS (flat mesh) and it performs only the limited functions set out in its discovery responses with respect to that finished product and Prolene Soft Mesh as a component part of the Prolift device. As such, Ethicon, LLC has little to no knowledge with respect to several of the topics listed in Plaintiffs' First Amended Notice.

The responses and objections contained herein are made without in any way waiving or intending to waive—but on the contrary reserving and intending to reserve—the right at any time to revise, supplement, correct, or add to these objections and responses. Although Plaintiffs noticed the deposition to occur in Morristown, New Jersey, on May 28, 2013, Defendant has advised Plaintiffs that its designated witnesses cannot be available that date and Defendant has provided alternative June dates. Further, Defendant will make its designees available for deposition in Puerto Rico.

SPECIFIC RESPONSES AND OBJECTIONS TO THE NOTICE

I. ETHICON, LLC COMPANY STRUCTURE AND ORGANIZATION

Topic 1a: The internal organizational structure of Ethicon, LLC's individual departments, groups, divisions, committees and/or task forces.

Response and Objections to Topic 1a: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendant.

Topic 1b: The organizational structure within each of Ethicon, LLC's departments, groups, divisions, and/or committees, including the identity of the individuals who performed work related to your pelvic mesh products.

Response and Objections to Topic 1b: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). The topic includes no time or scope limits. It is impossible for any witness to testify as to literally all of the "individuals who performed work related" to Gynemesh PS at Ethicon, LLC. Defendant further objects that some of the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the organizational charts, which Defendant has already produced to Plaintiffs as they were kept in the ordinary course of business. *See* F.R.Civ.P. 33(d).

Defendant invites Plaintiffs to meet and confer and attempt to narrow the topic to a manageable timeframe and scope. Subject to and without waiving any objections, Defendant will produce a witness to testify as to the identity of persons primarily and currently responsible for the different functions related to Gynemesh PS (finished product and component part), to the extent such information is reasonably available to Defendant.

Topic 1c: All persons, departments, and/or committees involved in the research, development, production, regulatory compliance, testing, packaging, distribution, sanitization, manufacturing and quality control of Ethicon, LLC's pelvic mesh products.

Response and Objections to Topic 1c: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). The topic includes no time or scope limits. It is impossible for any witness to testify as to literally all of the persons involved in the various listed functions related to Gynemesh PS. Defendant further objects that some of the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the organizational charts, which Defendant has already produced to Plaintiffs as they were kept in the ordinary course of business. *See* F.R.Civ.P. 33(d).

Defendant invites Plaintiffs to meet and confer and attempt to narrow the topic to a manageable timeframe and scope. Further, as noted in its discovery responses, Ethicon has entered an agreement with Ethicon, Inc. and MD&D whereby it relies on those entities' expertise with respect to certain of the listed topics, including research, development, and regulatory compliance. Defendant otherwise objects that this topic overlaps with the previous topic, and any intended differentiation between this topic and prior topic is vague and ambiguous.

Topic 1d: The functions, duties and responsibilities of each department, group, division, and/or committee related to the manufacturing of your pelvic mesh products.

Response and Objections to Topic 1d: Defendant objects that this topic overlaps with previous topics (Topic 1a,b,c) and any intended differentiation between this topic and the prior topics is vague and ambiguous.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to the prior topics.

Topic 1e: The members of Ethicon, LLC.

Response and Objections to Topic 1e: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on this topic to the extent such information is reasonably available to Defendant.

Topic 2: The nature, location, storage and organization of all documents and electronically stored information related to any activities of Ethicon, LLC, including any activities of its boards of directors and/or board of director committees and subcommittees, meeting minutes, reports, handouts and investigational documents from the date Ethicon, LLC first started manufacturing its pelvic mesh products (including but not limited to any of their component parts or materials used in the manufacturing process) until the present.

Response and Objections to Topic 2: Federal Rule of Civil Procedure 30(b)(6) requires that the deposition notice "describe with reasonable particularity the matters for examination." The purpose of this requirement is to permit the deponent to be able to prepare properly for the deposition, as the deponent may be asked to testify on matters outside of his or her personal knowledge. Defendant objects that this topic is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The topic is not limited in time as it requests information "from the date Ethicon, LLC first started manufacturing its pelvic mesh products …." The topic is not limited in scope as it requests "all" documents related to "any" activities and not just those activities related to pelvic mesh. Defendant objects that it is thus impossible for any witness to testify about all documents for all activities for all time.

Defendant further notes that it provided information with respect to this topic in its discovery responses. See, e.g., Response to Interrogatory Nos. 12, 17; Response to Document Request No. 6.

Defendant invites Plaintiffs to meet and confer and attempt to narrow the topic to a manageable timeframe and scope. Subject to and without waiving these Specific Objections, Defendants will produce a witness or witnesses whose testimony will address relevant document storage issues to the extent such information is reasonably available to Defendant.

Topic 3: The contractual relationship and the contracts with any and all vendors, suppliers or other third parties related to the supply of materials or component parts for the manufacture of the pelvic mesh products or in any way related to the manufacture of the pelvic mesh products.

Response and Objections to Topic 3: Defendant objects that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the copy of the contract with Secant and the Quality Agreement, which Defendant has already produced to Plaintiffs in the manner they were kept in the ordinary course of business. *See* Fed. R. Civ. P 33(d).

Subject to and without waiving these Specific Objections, Defendant will produce a witness or witnesses to testify on the topic to the extent such information is reasonably available to Defendant.

Topic 4: The structure of any working or functional department or group, committee, and/or task force including the identity of those individuals responsible for tracking, recording, reporting, handling, or following up on complaints, adverse events or other non-conformance issues or problems related to the manufacture of the pelvic mesh products.

Response and Objections to Topic 4: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly

burdensome, and provides insufficient notice under Rule 30(b)(6). Defendant further objects that it is impossible for a witness or multiple witnesses to testify as to the identity of all individuals responsible for the different applicable functions. See also Defendant's Response to Interrogatory No. 10.

Subject to and without waiving any objections, and to the extent the listed functions occur at Ethicon, LLC, Defendant will produce a witness or witnesses to testify as to the internal structure of the group(s) performing the function(s) related to Gynemesh PS (finished product and component part), to the extent such information is reasonably available to Defendant.

Topic 5: Ethicon, LLC's contract(s) and relationships with Medical Device and Diagnostics Global Services, LLC, including all aspects of the agreement and each parties' duties and responsibilities pursuant to the agreement.

Response and Objections to Topic 5: Defendant objects that the information sought in this topic is more readily available to Plaintiffs from other sources. Such information is included in the contract with Medical Device &Diagnostics Global Services, LLC, which Defendant has already produced to Plaintiffs. *See* Fed. R. Civ. P 33(d). Subject to and without waiving any objections, Defendant will produce a witness to testify on this topic, to the extent such information is reasonably available to Defendant.

Topic 6: The company organization and structure of Ethicon, LLC relating to the approval, management, administration, operation and compliance with any and all U.S. medical device regulations or standards applicable to your pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present.

Responses and Objections to Topic 6: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). Ethicon, LLC is not involved with and never has been involved with "developing" mesh products. Defendant further objects that this topic overlaps with previous topics (Topic 1a,b,c) and any intended differentiation between this topic and the prior topics is vague and ambiguous.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to the prior topics.

Topic 7: The company organization and structure of Ethicon, LLC relating to the approval, management, administration, operation and compliance with any and all foreign medical device regulations or standards applicable to your pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present.

Responses and Objections to Topic 7: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, is irrelevant and not likely to lead to the discovery of any admissible evidence, and provides insufficient notice under Rule 30(b)(6). Further, Ethicon, LLC is not involved with and never has been involved with "developing" mesh products.

II. MANUFACTURING AND DISTRIBUTION PRACTICES

Topic 1: The following manufacturing topics and the identity of all persons within Ethicon, LLC and all committees, groups, departments, and/or boards and the like (including their names, responsibilities, dates of operation and the identity of their members), who/which

were responsible at any and all time periods for the following from the date Ethicon, LLC first started manufacturing and distributing its pelvic mesh products until the present:

Response and Objections to Topic 1: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). The topic includes no time or scope limits and includes functions that do not exist at Ethicon, LLC. It is impossible for any witness to testify about "all persons" involved in the listed functions. Defendant further objects that some of the information sought in this topic is more readily available to Plaintiffs from other sources. Some of the information is included in the organizational charts, which Defendant has already produced to Plaintiffs as they were kept in the ordinary course of business and in an electronically searchable format. *See* F. R. Civ. P. 33(d).

Topic 1a: All raw materials, including additives, that are contained in the polypropylene mesh used in your pelvic mesh products, including the suppliers of all such products.

Response and Objections to Topic 1a: Ethicon, LLC does not have knowledge related to this topic concerning "raw materials."

Topic 1b: The existence and handling of manufacturing related complaints and non-conformance reports.

Response and Objections to Topic 1b: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on this topic, to the extent such information is reasonably available to Defendant.

Topic 1c: The method of supply and the identity of the suppliers of any and all materials or component parts of your pelvic mesh products.

Response and Objections to Topic 1c: To the extent encompassed by the topic, Ethicon, LLC does not have knowledge related to this topic concerning "raw materials." Subject to and without waiving any objections, Defendants will produce a witness or witnesses to testify on the topic to the extent such information is reasonably available to Defendant.

Topic 1d: Sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including those responsible for developing policies and procedures regarding sterilization and sanitization and those responsible for ensuring compliance with those policies and procedures.

Response and Objections to Topic 1d: Ethicon, LLC does not have knowledge related to the identity of "those responsible" for development of policies as Ethicon, LLC does not "develop" such policies and procedures. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic of the sterilization and sanitization of the plant and equipment, to the extent such information is reasonably available to Defendant.

Topic 1e: The maintenance of records regarding the sterilization and sanitization of the product, plant and equipment used in the manufacture of the pelvic mesh products, including maintaining and updating policies and procedures regarding sterilization and sanitization.

Response and Objections to Topic 1e: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic related to the maintenance of records regarding sterilization and sanitization of the plant and equipment, to the extent such information is reasonably available to Defendant.

Topic 1f: The specifications for all materials and/or component parts that make up your pelvic mesh products.

Response and Objections to Topic 1f: First, to the extent encompassed by the topic, Ethicon, LLC does not have knowledge related to this topic concerning "raw materials." Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). There are numerous specifications (and versions of those specifications) that have existed over the years relevant to Gynemesh PS. As a result, it is impossible for any witness to testify about "the specifications for all … component parts …." Defendant invites Plaintiffs to meet and confer to determine whether this request can be narrowed and to see if there is any particular specification(s) or specific aspects of the specifications to which Defendant's representatives can be prepared to testify.

Topic 1g: Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for finished products.

Response and Objections to Topic 1g: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic as to its one relevant finished product, Gynemesh PS (flat mesh finished product), to the extent such information is reasonably available to Defendant.

Topic 1h: Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product components.

Response and Objections to Topic 1h: Defendants object that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic

related to Gynemesh PS (component part), to the extent such information is reasonably available to Defendant.

Topic 1i: Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product raw materials.

Response and Objections to Topic 1i: Ethicon, LLC does not have knowledge related to this topic concerning "raw materials."

Topic 1j: End-to-end production process for pelvic mesh products, including the purchasing, testing and chemical composition of raw material, the extrusion of continuous filament, winding, weaving, knitting, scouring, and/or annealing.

Response and Objections to Topic 1j: Ethicon, LLC does not have knowledge related to this topic.

Topic 1k: Inspecting finished mesh products for surface effects and/or variations in the finished products.

Response and Objections to Topic 1k: Defendant objects that this topic overlaps with a previous topics (Topic 1.g) and any intended differentiation between this topic and the prior topic is vague and ambiguous.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to the prior topic.

Topic 1l: Measuring process variables, including temperature effects at the extrusion die, water content of the polymer, the finish of the tool and/or residual process materials that have not been completely removed through scouring.

Response and Objections to Topic 1l: Ethicon, LLC does not have knowledge related to this topic.

Topic 1m: Measuring polypropylene variables, including tacticity, presence of extrusion processing aids, monomers, dimers and/or residual catalyst.

Response and Objections to Topic 1m: Ethicon, LLC does not have knowledge related to this topic.

Topic 1n: Implementing and maintaining any manufacturing and distribution process tracking technologies employed by Ethicon, LLC, including but not limited to technologies such as RFID and barcodes and the means of collection, retention and integration of these data through the product lifecycle.

Response and Objections to Topic 1n: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1o: Installing, inspecting, maintaining, and operating equipment used to produce pelvic mesh products, including, but not limited to laser cutting equipment and mechanical cutting equipment used in the production of pelvic mesh.

Response and Objections to Topic 1o: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1p: The substantive preparation, printing, and placement of package inserts, product packaging, IFUs and other labeling for your pelvic mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto.

Response and Objections to Topic 1p: Ethicon, LLC does not have knowledge related to the topics of the substantive preparation and printing of package inserts, IFUs, or other labeling. Defendant further objects that some of the information sought in this topic is more readily available to Plaintiffs from other sources. Such information as to "in use" dates for IFUs has previously been provided to Plaintiffs. *See* F. R. Civ. P. 33(d). Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic of product packaging and placement of package inserts for its one relevant finished product, Gynemesh PS (flat mesh finished product), to the extent such information is reasonably available to Defendant.

Topic 1q: The substantive preparation and approval of any manufacturing process changes regarding your pelvic mesh products, including the specific dates and reasons for each change.

Response and Objections to Topic 1q: Defendant objects that this topic is overbroad, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). There is no limit in time nor scope. Defendant invites Plaintiffs to meet and confer to determine whether this request can be narrowed and to see if there is any particular process change to which Defendant's representatives can be prepared to testify. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic of the process of change control and change orders, to the extent such information is reasonably available to Defendant.

Topic 1r: Any investigation, evaluation and determination as to whether there is an association between manufacturing defects/problems/errors related to your pelvic mesh products and any adverse event experienced by a patient who was provided your pelvic mesh products.

Response and Objections to Topic 1r: See Response to Interrogatory No. 15. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic of complaint investigation, to the extent such information is reasonably available to Defendant.

Topic 1s: Any investigation, evaluation and determination as to whether there is an association or causal connection between your pelvic mesh materials, component parts or products and any adverse event or injuries.

Response and Objections to Topic 1s: Defendant objects that this topic overlaps with the previous topic and any intended differentiation between this topic and prior topics is vague and ambiguous. Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

Topic 1t: Any documents which pertain to or discuss personal injury litigation concerning your pelvic mesh product, including but not limited to documentation of litigation holds.

Response and Objections to Topic 1t: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1u: The maintenance of Ethicon, LLC's finances, budgets and expenditures related to its pelvic mesh products from the date first started developing and manufacturing its pelvic mesh products until the present.

Response and Objections to Topic 1u: Defendant objects that this topic is vague and ambiguous, in particular as to the phrase "finances . . . related to its pelvic mesh products," and

provides insufficient notice under Rule 30(b)(6). Defendant further objects that this topic is overbroad and unduly burdensome, in that, as written, it seeks information regarding every single expenditure related to products for a substantial time period. It is impossible for any witness to testify on every such expenditure over such a period of time. Further, Ethicon, LLC is not involved with and never has been involved with "developing" mesh products.

Subject to and without waiving any objections, Defendant invites Plaintiffs to engage in the meet and confer process to determine if this topic can be limited to an inquiry seeking relevant information narrowed in scope so that a witness could be prepared to testify on this topic.

Topic 1v: The interaction and communication internally or with any outside contractors, vendors or consultants regarding the manufacturing, engineering, distribution, regulatory compliance, or the safety of your pelvic mesh products for use by humans, from the date Ethicon, LLC first started developing and manufacturing pelvic mesh products until the present.

Response and Objections to Topic 1v: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, is irrelevant, and provides insufficient notice under Rule 30(b)(6). Further, Ethicon, LLC is not involved with and never has been involved with "developing" mesh products. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic of communications without outside contractors involving manufacturing and engineering issues, to the extent such information is reasonably available to Defendant.

Topic 1w: The interaction and communication internally or with any outside vendors regarding the safety of the use of the raw materials used in the manufacturing of your pelvic

mesh products, from the date Ethicon, LLC first started developing, packaging and/or manufacturing pelvic mesh products until the present.

Response and Objections to Topic 1w: Ethicon, LLC is not involved with and never has been involved with "developing" mesh products and has no knowledge related to the topic with respect to "raw materials."

Topic 1x: Any internal communications or external communication with vendors, suppliers, contractors or consultants related to whether polypropylene is safe for use in your pelvic mesh products.

Response and Objections to Topic 1x: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1y: The Corrective and Preventative Action Plan ("CAPA") relating to failure to properly maintain documents necessary for regulatory or litigation purposes.

Response and Objections to Topic 1y: Subject to and without waiving any objections, and if applicable to Ethicon, LLC, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1z: Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your pelvic mesh products.

Response and Objections to Topic 1z: Defendant objects that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, is irrelevant, and provides insufficient notice under Rule 30(b)(6). Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify

generally on the topic of material safety data sheets, to the extent such information is reasonably available to Defendant.

Topic 1aa: Any material safety data sheets or product safety sheets for the raw materials or component parts of your pelvic mesh products from the date you first started manufacturing your pelvic mesh products.

Response and Objections to Topic 1aa: Ethicon, LLC has no knowledge related to this topic with respect to "raw materials." Defendant also objects that this topic overlaps with the previous topic, and any intended differentiation between this topic and prior topics is vague, ambiguous, and repetitive.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

Topic 1bb: The Corrective and Preventative Action Plan ("CAPA") relating to failure of Prolene Mesh not being packaged (folded) as specified in the Process Specification for Packaging of Mesh Product.

Response and Objections to Topic 1bb: Assuming the topic relates to Prolene Mesh utilized for the treatment of SUI, Ethicon, LLC has no knowledge relating to this topic. Otherwise, Defendant objects that this topic is irrelevant and unlikely to lead to the discovery of any admissible evidence.

Topic 1cc: The Corrective and Preventative Action Plan ("CAPA") relating to Gynemesh non-absorbable Prolene Soft mesh not being properly sealed as well as evaluating units for packaging integrity.

Response and Objections to Topic 1cc: Subject to and without waiving any objections, and if applicable to Ethicon, LLC, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1dd: The Corrective and Preventative Action Plan ("CAPA") related to the increase in complaints with the TVT-Secur in Australia reported by Dr. Aran Maree.

Response and Objections to Topic 1dd: Ethicon, LLC has no knowledge relating to this topic.

Topic 1ee: The Corrective and Preventative Action Plan ("CAPA") related to defective inserter springs in the TVT-Secur.

Response and Objections to Topic 1ee: Ethicon, LLC has no knowledge relating to this topic.

Topic 1ff: Documentation of Investigations of causes of manufacturing nonconformities and corrective and preventative actions ("CAPA").

Response and Objections to Topic 1ff: Defendants object that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). Defendants Ethicon Inc. and J&J have already produced to Plaintiffs documentation concerning CAPAs as they were kept in the ordinary course of business and in an electronically searchable format. *See* F. R. Civ. P. 33(d). Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic of CAPAs, to the extent such information is reasonably available to Defendant.

Topic 1gg: The auditing of the conduct of the company and its officers and employees in connection with the manufacture, distribution, testing and quality of pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present.

Response and Objections to Topic 1gg: Defendants object that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). The topic is not limited in time nor scope. Defendant further objects to this topic as Ethicon, LLC is not involved with and never has been involved with "developing" pelvic mesh products. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic, to the extent such information is reasonably available to Defendant.

Topic 1hh: Ethicon, LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan and management review of the same.

Response and Objections to Topic 1hh: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1ii: Manufacturing standards for measuring space between pores of pelvic mesh products as well as evaluation and testing of the space between the pores.

Response and Objections to Topic 1ii: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1jj: Rejected Product that did not meet product specifications as well as the destruction or disposal of such product including records of the product.

Response and Objections to Topic 1jj: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1kk: The suppliers of the polypropylene mesh, including any contracts with any third parties about or relating to the supply of polypropylene mesh.

Response and Objections to Topic 1kk: Defendant objects that this topic overlaps with previous topics concerning contracts with third parties, including but not limited to I.3, and any intended differentiation between this topic and prior topics is vague, ambiguous, and repetitive.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

Topic 1ll: The existence of and terms of all hold harmless agreements or indemnification agreements between Ethicon, LLC and its vendors, suppliers, consultants, distributors or other manufacturers of pelvic mesh products.

Response and Objections to Topic 1ll: Defendant objects that this topic overlaps with previous topics concerning contracts with third parties, including but not limited to I.3, and any intended differentiation between this topic and prior topics is vague and ambiguous.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

Topic 2: The processes and procedures used by Ethicon, LLC in connection with processing of non-conformance reports, including the identification of policy manuals, SOPs, and safety manuals.

Response and Objections to Topic 2: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic of non-conformance reports and the applicable current SOPs, to the extent such information is reasonably available to Defendant.

Topic 3: The process and procedures for storing, testing and/or analyzing pelvic mesh products that have been returned to Ethicon, LLC due to complaints of malfunction or complications and the location of any and all such storage facilities.

Response and Objections to Topic 3: Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

III. OUTSIDE CONTRACTORS/ CONSULTANTS

Topic 1: All persons or entities that Ethicon, LLC (including the name, employer or the corporate entity the person is associated with, the time period in which the relationship existed, the title, role, function of the individual or entity, and a general description of the nature of the consultation or discussion) consulted with, paid or retained concerning your pelvic mesh products from the date Ethicon, LLC first started developing pelvic mesh products until the present. Areas of inquiry related to the identity of these consultants will include but will not be limited to the following:

Response and Objections to Topic 1: Defendant objects that: (a) it is impossible for any witness (or even multiple witnesses) to testify regarding "all persons or entities" since such communications and interaction would have occurred over the course of many years; (b) this topic is dramatically overbroad since there will be numerous consultants and interactions related to Gynemesh PS that have no bearing on this litigation; and (c) this is an improper topic for an

oral deposition as this information can be more efficiently transmitted by a document production regarding the particular communications Plaintiffs seek to discover. Further, Ethicon, LLC is not involved with and never has been involved with "developing" mesh products.

Subject to and without waiving any objections, Defendant invites Plaintiffs to engage in the meet and confer process to determine if this topic can be limited to an inquiry seeking relevant information narrowed in scope so that a witness could be prepared to testify on this topic.

Topic 1a: Ensuring and/or evaluating compliance with laws and regulations regarding product manufacturing.

Response and Objections to Topic 1a: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1b: Ensuring and or evaluating compliance with quality manufacturing procedures and policies, included but not limited to auditing of procedures such as ISO 9000 and any similar procedures.

Response and Objections to Topic 1b: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1c: Any consultants involved in responding to any perceived deficiencies to Ethicon, LLC's processes or manufacturing, including Corrective and Preventative Actions, (CAPA's) Product Quality Issues (PQI's), or nonconformance issues or problems.

Response and Objections to Topic 1c: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1d: Any consultants involved with testing, maintenance, repair, setup and operation of plant equipment.

Response and Objections to Topic 1d: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1e: Any scientific, manufacturing, and engineering consultants.

Response and Objections to Topic 1e: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1f: Any product testing consultants.

Response and Objections to Topic 1f: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1g: Any machine testing consultants

Response and Objections to Topic 1g: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Subject to and without waiving any objections, Defendant will produce a witness or

witnesses to testify on the topic, to the extent such information is reasonably available to Defendant.

Topic 1h: Any consultants or contractors involved with the supply of mesh, the type of mesh to be used in the pelvic floor mesh products, or the safety of the mesh to be used in the pelvic floor mesh products.

Response and Objections to Topic 1h: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Ethicon has no knowledge related to the topics of "the type of mesh to be used in the pelvic floor mesh products, or the safety of the mesh to be used in the pelvic floor mesh products." Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify on the topic related to the supply of mesh, to the extent such information is reasonably available to Defendant.

Topic 2: Ethicon, LLC's third party consultants or entities retained for Manufacturing, Engineering, Product Testing, Auditing, and the nature of the work done by those consultants and the time periods during which they were retained from the date Ethicon, LLC first started developing pelvic mesh products until the present.

Response and Objections to Topic 2: Defendant objects that this topic overlaps with previous topics, including I.3, and any intended differentiation between this topic and prior topics is vague, ambiguous, and repetitive. Further, Ethicon, LLC is not involved with and never has been involved with "developing" mesh products.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

VI. REGULATORY COMMUNICATIONS

Topic 1: All interactions between Ethicon, LLC and the FDA or other regulatory bodies in the United States concerning Ethicon, LLC's manufacturing or distribution of pelvic mesh products or component parts making up such pelvic mesh products, including the location, storage and organization of any and all documents that relate to or reflect the same.

Response and Objections to Topic 1: Ethicon, LLC refers Plaintiffs to the Quality Agreement. Defendants object that this topic is overbroad, fails to state the topic with reasonable particularity as required by the Rule, is unduly burdensome, and provides insufficient notice under Rule 30(b)(6). Further, the topic includes no time limits, and it is impossible for any witness or multiple witnesses to testify about "all interactions" with FDA. Subject to and without waiving any objections, Defendant will produce a witness or witnesses to testify generally on the topic of interactions between Ethicon, LLC and the FDA, to the extent such information is reasonably available to Defendant.

Topic 2: Communications between Ethicon, LLC and the FDA or other federal government entity or agency regarding the manufacturing of pelvic mesh products.

Response and Objections to Topic 2: Defendant objects that this topic overlaps with the previous topic, and any intended differentiation between this topic and prior topics is vague, ambiguous, and repetitive.

Defendant invites Plaintiffs to meet and confer to determine whether there is any aspect of this topic that is not already being addressed by testimony that Defendant has agreed to provide in response to prior topics.

DOCUMENT REQUESTS

Document Request No. 1: All documents relied upon by the deponent in preparing for this deposition.

Responses and Objections to Document Request No. 1:

Defendants object that this request seeks information protected by the attorney work product doctrine. *See, e.g.*, *Hickman v. Taylor*, 329 U.S. 495, 511 (1947); *In re Allen*, 106 F.3d 582, 608 (4th Cir. 1997) (observing that "choice and arrangement [of documents in witness's personnel file by counsel for witness] constitutes opinion work product because [counsel's] section and compilation of these particular documents reveals her thought processes and theories regarding this litigation"); *Rhodes v. E.I du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (Goodwin, C.J.) ("Courts acknowledge that the document selection process represents the mental impressions of the party's counsel and is protected work product." (internal quotation marks and alterations omitted)). Subject to and without waiving any objection, Defendants note that each and every document relied upon by the deponent in preparing for this deposition has already been produced to Plaintiffs.

Document Request No. 2: All documents reflecting correspondence between the FDA and Ethicon, LLC regarding pelvic mesh products or facilities and procedures involved in the manufacture of pelvic mesh products.

Responses and Objections to Document Request No. 2:

To the extent responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 3: All current and former product specifications for pelvic mesh products including draft copies.

Responses and Objections to Document Request No. 3:

Ethicon, LLC objects as this request is irrelevant, overly broad and unduly burdensome. Subject to and without waiving this objection, to the extent responsive, non-privileged current documents exist, they have been or will be produced.

Document Request No. 4: Ethicon, LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan as well as minutes and notes management review meetings regarding these documents.

Responses and Objections to Document Request No. 4:

Ethicon, LLC objects as this request is irrelevant, overly broad, and unduly burdensome. Subject to and without waiving this objection, to the extent responsive, non-privileged current documents exist, they have been or will be produced.

Document Request No. 5: Any documents indicating or discussing deviation from product specifications, including but not limited to, fraying, bunching, curling, degradation, fading, crumbling, folding, toxicity or sizing of mesh.

Responses and Objections to Document Request No. 5:

Ethicon, LLC objects as this request is irrelevant, overly broad and unduly burdensome. Subject to and without waiving this objection, to the extent responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 6: Records of product that was rejected and destroyed or otherwise disposed for not meeting product specifications.

Responses and Objections to Document Request No. 6:

Ethicon, LLC objects as this request is irrelevant, overly broad and unduly burdensome. Subject to and without waiving this objection, to the extent any responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 7: All agreements between Ethicon, LLC and third parties or consultants related to the supply of mesh for use in pelvic floor products.

Responses and Objections to Document Request No. 7:

To the extent responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 8: All documents related to whether the use of polypropylene mesh is safe for use in humans.

Responses and Objections to Document Request No. 8:

Ethicon, LLC objects as this topic is overly broad. Subject to and without waiving this objection, to the extent any responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 9: Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your pelvic mesh products.

Responses and Objections to Document Request No. 9:

Ethicon, LLC objects as this topic is overly broad. Subject to and without waiving this objection, to the extent responsive, non-privileged documents exist, they have been or will be produced.

Document Request No. 10: Any material safety data sheets or product safety sheets for the raw materials or component parts of your pelvic mesh products from the date you first started manufacturing your pelvic mesh products

Responses and Objections to Document Request No. 10:

Ethicon, LLC objects as this topic is overly broad. Subject to and without waiving this objection, to the extent any responsive, non-privileged documents exist, they have been or will be produced.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on May 9, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.